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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,986

12/15/2005

Eliot Bloom

PA1766

3739

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
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EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

NOTIFICATION DATE

DELIVERY MODE

03/17/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No. 10/560,986	Applicant(s) BLOOM ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/15/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 11/13/09 is acknowledged.
2. Claims 22-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Information Disclosure Statement

3. The information disclosure statement(s) (IDS) submitted on 12/15/05 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

Drawings

4. The drawings filed on 12/15/05 are acceptable.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claim 6 recites the limitation "the at least one deformation element" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It is believed that claim 6 should be dependent upon claim 5 instead of claim 1.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4, 8, 10-13, 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,348,064 to Kanner.

Kanner discloses a device that is capable of contracting tissue, the device comprising a body 10 having a longitudinal axis (see ref. no. 100 in Fig. 1), and a plurality of legs 12A-12C, each leg having one end coupled to the body and being radially splayed about the axis (see Fig.1), each leg including a snap-acting spring tip 18A-18C (the legs can be made of elastic materials such as nitinol; col. 7, ll. 48-50); wherein each leg is capable of transformation between a deployment state (Fig. 1-2) and a treatment state (Fig. 3); wherein each spring tips are closer to the longitudinal axis when the legs are in the treatment state (Fig. 3); wherein each tips are pointed (spicules); wherein the device can be made of titanium, stainless steel or nitinol, which is radiopaque (col. 4, ll. 20-25); wherein the device is fully capable of shortening a radial dimension of a mitral valve annulus; wherein a delivery catheter 512 is used to deliver the device; wherein a guidewire 502 is slidably received within a lumen of the delivery catheter; wherein the delivery catheter has a compression device (the distal end portion with the seam 700); wherein delivery catheter has a position device (dilator 520); wherein the delivery catheter has a guiding sheath 512, a holding tube 606, a push tube

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604; wherein the legs are radially compressed while within the delivery catheter, and wherein the legs are expanded when released from the delivery catheter.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kanner in view of US 4,610,251 to Kumar.

Kanner, as provided in the rejections above, discloses all the limitations of the claim except for each legs having two tip members. However, providing two tip members in a staple is well known in the art, as shown in Figs. 1-6 of Kumar.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kanner to include two tip members as having two tip members would provide better securement of the staple to the tissue.

14. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanner in view of US 5,342,396 to Cook.

Kanner, as provided in the rejections above, discloses all the limitations of the claims except for each legs having a deformation element. However, Cook discloses a staple that uses a notch 305 as a deformation element in order to allow the tips of the staple to bend inwardly. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the legs of the device of Kanner to include deformation elements because it would allow the tips to bend inwardly, which would provide more tension against the tissue and better secure the staple to the tissue.

15. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kanner in view of US 4,635,637 to Schreiber.

Kanner, as provided in the rejections above, discloses all the limitations of the claim except for each legs having a barb directed towards the body. However, Schreiber discloses a staple that has barbs 30,32. Therefore, it would have been

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obvious to one of ordinary skill in the art at the time the invention was made to add barbs to the legs of Kanner since it would prevent the staple from accidentally backing out of the tissue.

16. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kanner in view of US 7,112,214 to Peterson et al.

Kanner, as provided in the rejections above, discloses all the limitations of the claim except for the device including a therapeutic agent. However, providing a therapeutic agent on a staple fastener is well known in the art, as taught by Peterson in col. 11, ll. 8. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kanner to include therapeutic agent since it would also help treat the fastened tissue with medication.

17. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kanner in view of US 5,269,759 to Hernandez, et al.

Kanner, as provided in the rejections above, discloses all the limitations of the claim except for the guidewire being magnetic. However, magnetic guidewires are well known in the art, as disclosed by Hernandez. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a magnetic guidewire in the device of Kanner since it has been held that a mere simple substitution of one known element for another will yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

18. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanner in view of US 6,022,372 to Kontos.

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Kanner, as provided in the rejections above, discloses all the limitations of the claims except for the delivery catheter having a balloon catheter. However, using a balloon catheter with a stapling device is well known in the art, as disclosed by Kontos (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a balloon catheter in the device of Kanner since it would help support the vascular tissue (if the target tissue is a blood vessel). The balloon would act as a positioning/compression device.

19. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kanner.

Kanner discloses all the limitations of the claim except for the legs being self-expandable. However, the examiner takes Official notice that using self-expandable material on a staple/clip fastener is well known in the art and would be obvious to one of ordinary skill in the art.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773